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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with Vidita Choudhry, Ph.D., Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892-2479; telephone: 301-594-4095; email: vidita.choudhry@nih.gov. A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

High-Throughput COVID-19 Diagnostic Test that Detects Both Viral and Host Nucleic Acid

The virus that causes COVID-19 is designated severe acute respiratory syndrome

coronavirus 2 (SARS-CoV-2). The rapid worldwide spread and impact of COVID-19 has created a need for accurate, reliable, and readily accessible testing on a massive scale. The subject invention describes development of a massively paralleled multiplexed screening method using next generation sequencing (NGS). This method uses sample-specific barcoded indexes that detect both SARS-COV-2 virus and the host's transcriptional response to infection simultaneously. By matching existing laboratory protocols for PCR-based sample processing, this assay is easily incorporated into existing CLIA-certified facilities. This testing approach provides the capability for testing tens of thousands of patient samples in a large bolus, allowing accurate and fast-turnaround SARS-CoV-2 testing capacity at population scale, and permits massive scale monitoring of at-risk individuals with minimal processing delay.

Potential Commercial Applications:

Diagnostic test for detecting infectious organisms, including SARS-CoV-2.

Competitive Advantages:

- Reduction in reagents needed to perform a test, reducing test cost and bottleneck of critical reagents used during nucleic acid amplification.
- Simultaneously detect the pathogen and a host's transcriptional response to infection by the pathogen.
- Gene expression information from the donor can be used to predict disease severity.

Development Stage:

- Early stage
- Data from tests of human samples available

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Intellectual Property: HHS Reference No. E-241-2020-0; U.S Provisional Patent Application 63/116,031 filed November 19, 2020.

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This notice is made in accordance with 35 U.S.C. 209 and 37 CFR Part 404.

Dated: January 08, 2021.

Bruce D. Goldstein,

Director,

National Heart, Lung, and Blood Institute,

Office of Technology Transfer and Development.

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